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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,795	12/16/1999	NING ZHANG	PXE-007.US	8087

23419 7590 05/21/2003

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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N		Applicant(s)	
	09/464,795		ZHANG ET AL.	
	Examiner		Art Unit	
	Ram R. Shukla		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38, 40, 41, 43, 45, 46, 49, and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38, 40, 41, 43, 45, 46, 49 and 65-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

1. The response filed 3-6-03 has been received and entered.
2. Claims 38, 40, 41, 43, 45, 46, 49, and 65-68 are pending and under consideration.

Information Disclosure Statement

3. As noted in the previous office actions of 9-13-01 and 8-27-01, the information disclosure statement filed 6-25-01 fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

It is noted that applicants did not address this issue in their response.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 38 and 65-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the previous office action of 2-1-01, 9-13-01, 8-27-02 and as discussed below.

Response to Arguments

Applicant's arguments filed 8-28-02 have been fully considered but they are not persuasive. Applicants argue that it is legally or factually incorrect to assert that the phenotype of the claimed animals would be unpredictable. In response it is emphasized that the office actions listed above used scientific articles that support

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the stand taken in the office action and the applicants have not provided any evidence to support their arguments. It is agreed that applicants do not have make the invention, however, they have to describe the invention to show the possession and the applicants have not met this burden. Use of the transgenic animals as a disease model is not relevant because the issue is of the unpredictability of the getting a certain phenotype or what phenotype and the art of Wood et al uses the example of disease model as an example to discuss the issue. Applicants' arguments that Wood, Cui and Cameron references do not establish unpredictability is not persuasive. Applicants arguments that animals are useful simply by virtue of integration of the expression cassettes is besides the point since the issue is not the utility rather the description of the invention. It is emphasized that the Wood, Cui and Cameron are articles that discuss transgenic technology in general and therefore, they do establish the unpredictability of the art of making transgenic animals and what characteristics such animals will have. Applicants have not provided any factual evidence to support their arguments.

Next, applicants argue additional evidence of record, US patent 6,217,847 and the declaration by Dr. West, however, none of these provide any evidence to address the issues raised in the rejections. The declaration by Dr. West was discussed in detail in the previous office action and therefore the discussion will not be repeated here. However, it is repeated that Dr. West's declaration did not provide any factual evidence except for arguing that Cameron and Cui arts were not relevant. It is reiterated that applicants argument alone cannot take place of evidence lacking in the record (see In re Scarbrough 182 USPQ, (CCPA) 1979).

6. Claims 38, 40, 41, 43, 45, 46, 49, and 65-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for reasons of record set forth in the previous office action of 2-1-01 and 9-13-01, 8-27-02 and discussed below.

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Applicant's arguments filed 3-06-03 have been fully considered but they are not persuasive.

Applicants have argued that by requiring actual production of the claimed animals, the office has not applied proper enablement standards. Applicants' arguments are not persuasive because no such requirement has been applied rather the enablement issue has been analyzed based on the 112 first paragraph guidelines of MPEP. Applicants' arguments that the even relatively out-dated PTO training materials recognize the claims to transgenic animals are fully enabled are not persuasive because each patent application is examined based on its own merits and therefore the analysis is case specific. Applicants' arguments that the enabled use of transgenic animals comprising expression cassettes (US Patent 6,217,847) is well documented is not persuasive because as discussed in the previous office actions the transgenic animals of with one transgene can not be predictive of the enablement of making and using of another transgenic animal with another transgene(s). Applicants have reiterated their argument that Wood, Cameron and Cui are not germane to the claimed animals. However, as discussed in the written description rejection, these arguments are not persuasive because the cited articles review the general state of the unpredictability of the art of making and using the transgenic animals.

Next applicants argued that the examiner erred in dismissing the 132 declaration and Jankowsky art and that the declaration was not properly considered. Again, applicants' arguments are not persuasive because the declaration as well as the art cited were discussed in detail. It is not argued that the post filing art can not be used in support of enablement, but the post-filing art has to have used the same method as taught in the specification and there was not evidence such was the case instantly. The level of ordinary skill in the art two years after the filing date of an application is not same as that at the time of the filing of the application if the method disclosed in the art and in the specification are not the same.

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Regarding applicants argument about the 132 declaration, it is noted that the declaration was extensively discussed and the discussion from pages 4-5 of the office action of 8-27-02 is reiterated below:

"Applicants have provided a 132 declaration by David West and have quoted paragraphs 6-10 and 13 of the declaration. Dr West has stated that at the time of the invention, specification conveyed to an artisan of skill that the inventors had possession of the invention since the invention teaches how to make the invention. It is reiterated that this is the same argument as the applicants have put forth and which has been addressed above. Accordingly, the discussion put forth above is not repeated. Next, the declaration states the expression constructs, polynucleotide components of the expression constructs were in the possession of the inventors and since an operative method of making the transgenic mouse is described in the specification, inventors had possession of the invention. Furthermore, the declaration states that such methods were routine in the art and the reference by Jankowsky was quoted to support the point that the method was routine. In response, it is noted that, first, the cited reference was published in 2001, two years after the filing date of the application and second, applicants have not provided any evidence that the method used by Jankowsky is the same as that disclosed in the specification. Therefore, the cited reference cannot be used to indicate that the state of the art or for supporting description at the time of the invention. Rest of the arguments and statements made in the declaration are the same as those discussed in the arguments by the applicants. It is noted that the declaration in paragraphs 9-11 only reiterates what is described in the specification and does not provide any evidence that would support the applicant's arguments that they had possession of the claimed invention at the time of the invention.

The declaration in paragraph 12 states that the art by Cameron and Cui are not relevant because Cameron is focused on livestock and that animals with desired expression could be selected and used and that integration event is not relevant as long as the stress inducible element controlled the expression. Likewise the declaration has argued that cui is irrelevant since it is not for light generating proteins. In response, it is noted that both the arts are relevant since they describe

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the state of the art of making transgenic mammals and that production of a transgenic mouse is dependent on several factors, which make the art unpredictable and Cui art discussed reporter gene transgenic mouse. It is noted that luciferase is a reporter gene and calling it by another name does not alter its limitations or use as reporter gene. In summary, the declaration does not provide any new or further evidence except for reiterating the arguments made by the applicants in their response to the office action of 9-13-01."

It is reiterated that the declaration was fully considered and discussed and the applicants' arguments that the declaration was not considered is not persuasive.

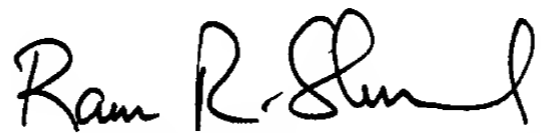
In summary, since the of the art of making of transgenic mice is highly unpredictable and unless a transgenic mouse has been produced, one can not predict what will the characteristics of the transgenic mouse comprising a given panel of expression constructs and therefore, an artisan would not know how to use the claimed transgenic mouse in claimed methods.

7. No claim is allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



RAM SHUKLA
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632